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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,457	10/16/2001	Joseph J. Chang	56301P579D	5126

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WOOD, HERRON AND EVANS
2700 CAREW TOWER
CINCINNATI, OH 45202

EXAMINER

STIGELL, THEODORE J

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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06/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/978,457	Applicant(s) CHANG, JOSEPH J.	
	Examiner THEODORE J. STIGELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 15-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 15-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, and 15-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Luther (4,964,854). Luther discloses a needle cannula (26) having a distal point, a proximal end and further having a shaft with a circumference, a tip protector (40) having a base, the tip protector defining an opening to receive the needle cannula shaft and the tip protector is slideably mounted thereon, blocking means (50, 54) coupled to the tip protector for blocking the tip protector opening so as to enclose the distal point of the needle cannula within the tip protector, a gasket (60) coupled to the tip protector base defining an opening of a size to receive the needle cannula shaft, impeding means (29) fixedly coupled to the needle cannula shaft at a predetermined location of the shaft for impeding movement of the tip protector along the needle cannula shaft beyond a pre determined distance from the needle cannula distal point, further comprising a flash chamber (36) coupled to the needle cannula at the needle cannula proximal end, wherein the blocking means comprises a tab (50, 54) having a length sufficient to block the tip protector opening, the tab pivotably coupled to the tip protector within the tip protector opening and slideably engaging the needle cannula

shaft in a first biased position such that upon removal of the needle cannula shaft the tab is free to pivot to a second position extending across the tip protector opening, wherein the impeding means comprises an irregularity in the needle cannula shaft circumference a pre-determined distance from the needle cannula distal point occluding passing of the needle cannula shaft through the gasket opening.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11 and 15-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jagger et al. (4,781,692) in view of Chang et al. (5,419,766). Jagger discloses an apparatus with a cannula (100) and slidable tip protector (106) that includes most of the limitations recited by the applicant. Jagger does not disclose a blocking means to protect the opening of the tip protector. Chang discloses an

apparatus with a cannula and slidable tip protector that includes blocking means (15) for the opening. The blocking means is useful in preventing the distal tip of the cannula from protruding from the tip protector after the cannula has been used. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the protector of Jagger with blocking means, as taught by Chang, to make a device that was better able to prevent accidental needle sticks.

Claims 8, 10-11, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luther (4,964,854). Luther discloses the claimed invention except for teaching that the tabs are made of metal and the tip protector is made of a transparent material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use these materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Response to Arguments

Applicant's arguments filed 2/14/2008 have been fully considered but they are not persuasive.

Luther 4,964,854

In response to the applicant's argument that Luther does not disclose a gasket defining an opening through which the needle shaft is movable, the examiner respectfully disagrees. The applicant contends that the term "gasket" is understood to define a seal, sufficient to provide a blood-wiping action about the needle shaft as the

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needle tip is pulled into the tip protector. The examiner maintains that this is not a commonly accepted definition of the term "gasket" and further notes that the applicant has not specially defined "gasket" in the specification. The examiner maintains that the applicant is reading limitations from the specification into the claims. The examiner notes that Merriam-Webster's On-line Dictionary defines gasket as "a material (as rubber) or a part (as an O-ring) used to make a joint fluid-tight". The examiner contends that element (60) provides a fluid tight engagement between the ring (62) and the body (42) and therefore meets the limitations of a gasket. The examiner also maintains that there are no recited limitations that require the gasket to provide a fluid-tight seal around the needle shaft.

Jagger et al. (4,781,692) and Chang et al. (5,419,766)

In response to the applicant's argument that it would not be obvious to combine Jagger and Chang to make the claimed invention, the examiner respectfully disagrees. The applicant's main point seems to be that element (106) is the only structure to modify with the blocking means and therefore even if it were obvious to combine the references, the blocking means would still not be capable of performing the recited functions. The examiner agrees that it would not be obvious to modify the tubular part of (106) below element (114) with the blocking means, but maintains that it would be obvious to include the blocking means at the distal end of (106) and also in (104). The combination is proper because both references are analogous art. Also, one skilled in the art would recognize that needle stick accidents are a serious problem in the intravenous access device art. One skilled in the art would also recognize that Chang

provides a blocking means to prevent such accidents. Chang's blocking means is designed to be used in systems wherein a sharp cannula provides access and insertion to the body for a softer catheter. One skilled in the art would recognize that Jagger is such a system and could therefore be modified to include the blocking means of Chang.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763